

## Remarks

Claims 24 and 26 - 47 are pending. Favorable reconsideration is respectfully solicited.

The subject invention is directed to novel copolymers containing silicone moieties and greater than or equal to 50 weight percent of moieties derived from copolymerizing, with a polymerizable silicone moiety, at least one vinyl ester of an optionally branched C<sub>1-15</sub> carboxylic acid, preferably vinyl acetate. The copolymers are prepared by a process of solution polymerization in at least two organic solvents, at least one of which has a transfer constant C<sub>s</sub> relative to vinyl acetate  $> 20 \times 10^{-4}$  at 70°C. As a result of the unique polymerization process, a polymer solution is obtained, and when solvent is removed, transparent solid polymers which are thermoplastically processable are obtained.

Claim 24 has been amended by incorporating the limitations of claim 25, which has now been cancelled (claims 38 - 46 have thus been amended to be dependent upon claim 24). The melt viscosity of 5 to 30,000 mPa·s at 100° - 140° means that these polymers are easily melted to form low viscosity melts which can readily be thermoplastically processed, for example by roll coating, gravure printing, injection molding, etc. By way of example, the upper end viscosity of 30,000 cps is less than that of Ketchup (50,000 mPa·s) (Heinz Ketchup is higher, 50 - 70,000 mPa·s), and somewhat more viscous than olive oil (10,000 mPa·s or Hershey's chocolate syrup (10,000 - 25,000 mPa·s)).

That the process employed to make the polymers results in a different product is evident from the examples and comparative examples. In each of Comparative Examples 1, 3, and 4, a vinyl acetate copolymer was prepared by solution polymerization in ethyl acetate (single solvent). Each polymer contained about 11% copolymerized silicone. In Example 1, a two phase solution resulted, and following removal of solvent, a hard, cloudy white resin with a molecular weight Mw of 65,325 and a polydispersity of 3.15 was obtained. The

polymer exhibited two glass transition temperatures, one for silicone (-121°C) and one for polyvinyl acetate (34.1°C).

In Comparative Example 3, the process was slightly different, but the same monomers and monomer ratios as in Comparative Example 1 were employed, again with a single solvent, ethyl acetate. The reaction mixture gelled, and a crosslinked, solvent swollen product was obtained which was impossible to further work up.

In Comparative Example 4, again the process was varied but monomer content and solvent were identical. A polymer with molecular weight  $M_w$  of 135,808 and polydispersity of 5.8 was obtained. The polymer again exhibited two Tgs, -123°C and 32.8°C. The polymer was white and crosslinked.

Example 5 employed the same monomers in the same proportions as in Comparative Examples 1, 3, and 4, but in addition to ethyl acetate also employed isopropanol ( $C_s = 44.6 \times 10^{-4}$ ). The polymer obtained was very different from those of the comparative examples, being soluble in the solvent mixture (1 phase), and following isolation, was a transparent solid with molecular weight  $M_w = 14,521$ , a polydispersity of only 2.67, and but a single Tg of 30.8°C. Example 2 exhibited similar results, with a higher silicone content. At the higher silicone content the transparency of the polymer was even more surprising.

These experimental results indicate that the method of preparation results in very surprising and non-obvious differences in the polymer. With the single solvent, cloudy crosslinked polymers with two glass transition temperatures are generally obtained, while when the inventive process is employed, transparent thermoplastic polymers are obtained.

Claims 27, 28, 30, and 35 - 37 have been objected to only, but indicated to be allowable if rewritten in independent form, containing all the limitations of base claim 24 and any intervening claims. This has been done. Claims 27, 30, and 35 are now independent

claims. Claims 28 and 36 - 37 are dependent on claims 27, 35, and 35 respectively. These claims should thus be allowable.

Claims 24, 25, 29, 31 - 34 and 38 - 46 have been rejected under 35 U.S.C. § 102(b) or alternatively under 35 U.S.C. § 103(a) as unpatentable over Ito (as U.S. 6,727,336) ("*Ito*"). Claim 47 has been rejected separately under 35 U.S.C. § 103(a) over *Ito*. Applicants respectfully traverse these rejections.

*Ito* is directed to addition polymerizable mixtures which cure to duroplasts (crosslinked thermoset resins) useful for contact lenses. Applicants agree with the Examiner that these polymers may be solid and transparent<sup>1</sup>. However, they clearly are highly crosslinked, since they are hydrogels, and can even be saponified at elevated temperature, up to 100°C, without losing their shape, i.e. the completed contact lens can be boiled in aqueous alkali, converting vinyl acetate moieties to more hydrophilic vinyl alcohol moieties, *see, e.g.* column 14. The resulting saponified polymer, despite its high hydrophilicity, is not water soluble, indicative of its crosslinked structure.

Due to the means of preparation employed by Applicants, Applicants' polymers are, in contrast to *Ito*, not highly crosslinked, but instead have very low melt viscosities which render them thermoplastically processable. While *Ito's* polymers are duroplasts and do not melt, Applicants' polymers behave as typical thermoplastics.

When Applicants' polymers are saponified, rather than retain their solid nature, they dissolve to form aqueous solutions. While *Ito's* polymers are swollen but not dissolved by organic solvents, Applicants' polymers are soluble in organic solvents, allowing them to be coated onto substrates in solution form.

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<sup>1</sup> But not necessarily so, since *Ito* cautions in many portions of his application that cloudy polymers, still within the scope of his claims, may be obtained under certain circumstances.

The above should be sufficient to show that the mode of preparation employed by Applicants' with two organic solvents, one having a transfer coefficient  $> 20 \times 10^{-4}$ , results in different polymers as compared to those prepared by the process of *Ito*. One skilled in the art would have no desire to modify *Ito* to prepare a subject invention polymer, since *Ito* desires to make a three dimensionally crosslinked hydrogel which retains its shape even at 100°C, while Applicants' polymers are liquid in the range of 100° - 140°C, as indicated by their melt viscosities. Many of Applicants' polymers melt below 100°C. *Ito's* polymers, when saponified, retain their shape and are not water soluble, while Applicants' polymers, under the same conditions, dissolve. One skilled in the art would certainly not desire to produce a water soluble contact lens. Such a lens would dissolve while in the wearer's eye.

Withdrawal of the rejections over *Ito* is solicited.

Claims 24, 25, 29, 31 - 34, and 38 - 46 have been rejected under 35 U.S.C. § 102(b) or alternatively under 35 U.S.C. § 103(a) over Mueller et al. U.S. 4,136,250 ("*Mueller*"). Claim 26 has been separately rejected over *Mueller* under 35 U.S.C. § 103(a). Applicants respectfully traverse these rejections.

*Mueller* is directed to water-insoluble hydrophilic gels which are intended for the most part for use in sustained drug release systems. At least some of the *Mueller* hydrogels may be transparent, since he does suggest their use for contact lenses<sup>2</sup>. The *Mueller* hydrogels are prepared by copolymerizing an unsaturated silicone moiety with a water soluble monomer. It is noted that Applicants' vinyl ester monomers are not water soluble monomers. *Mueller* also allows for water insoluble monomers (such as vinyl acetate), but only when used with a water soluble monomer.

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<sup>2</sup> The fact that both *Mueller* and *Ito* also allow for non-transparent polymers would appear to preclude a rejection under 35 U.S.C. § 102(b) under principles of inherency, since for inherency to apply, transparent polymers (of the claimed melt viscosity, etc.) must be a necessary result, not a possible or even probable result.

All of *Mueller* polymers are cross-linked (duroplastic) hydrogels. *See, e.g.* column 3, lines 38 - 40. The polymers have no thermoplastic nature, and unlike the subject invention polymers which are produced by solution polymerization and are obtained, prior to drying, as a solution in organic solvent, *Mueller's* gelled, crosslinked polymers swell in organic solvents. *See, e.g.* column 10, lines 60 - 64, and column 12, lines 8 - 14. At column 13, line 33 to column 14, line 1, fragrances, including ethyl acetate, can be incorporated as a swollen hydrogel. Applicants' polymers dissolve in ethyl acetate. Withdrawal of the rejections of the claims over *Mueller* is solicited.

Further difference between both *Ito* and *Mueller* are apparent from their respective disclosures. It is noted, for example, that duroplast articles are prepared both by *Ito* (contact lenses) and *Mueller* (films) by curing of the monomers in the form of the desired article, a method of preparation commonly employed with crosslinked thermoset polymers. In both cases, the monomers can be supplied dissolved in or diluted with solvent, however, the solvent can remain in the article. A solvent-swollen hydrogel article results. In the case of the subject invention, however, when solvents are employed, for example when coating substrates, no coating (film, article) is produced until the solvent evaporates. This behavior is due to the thermoplastic nature of Applicants' polymers, in contrast to the thermoset nature of those of the art. In the prior art, once an article, *e.g.* a film is formed, solvent may be removed, but the film, being duroplastic, is not solvent-soluble. In contrast, Applicants film, once formed, can be removed by dissolving in solvent, as with conventional thermoplastics. One skilled in the art immediately recognizes the substantial differences between the prior art swellable, crosslinked, not-thermoplastically processable hydrogel polymers and the low melt viscosity thermoplastically processable polymers of the subject invention. It is the process of preparation of the claimed polymers, process steps which are recited in the claims, which produces this striking difference. Neither reference teaches or suggests Applicants' process for producing the claimed polymers, which cannot be used for the purposes to which the prior art is directed. Withdrawal of all rejections of record is solicited.

Entry of the amendments to the claims is solicited, as first, the rejections are new of record and Applicants have had no prior opportunity to address these; second, the amendments to claims 27, 30, and 35 make these claims and their respective dependent claims allowable; and third, no new issues are raised, since claim 25 was previously pending, dependent on claim 24, thus the scope of claim 24 is the same as the former scope of claim 25.

Applicants submit that the claims are now in condition for Allowance, and respectfully request a Notice to that effect. If the Examiner believes that further discussion will advance the prosecution of the Application, the Examiner is highly encouraged to telephone Applicants' attorney at the number given below.

Please charge any fees or credit any overpayments as a result of the filing of this paper to our Deposit Account No. 02-3978.

Respectfully submitted,

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Date: June 19, 2007

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